

Appendix D
PREMARKET NOTIFICATION [510(k)] Summary

*510(K) Summary of Safety and Effectiveness
Premarket Notification 510(k)*

K081214

Zap Lasers, LLC
2621-B Pleasant Hill Road
Pleasant Hill, Ca. 94523

MAY 14 2008

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: *Styla MicroLaser™/StylaOrtho™*
Common Name(s): Surgical Laser System
Classification Name(s): Laser, Surgical

2. Establishment Name & Registration Number:

Name: Zap Lasers, LLC
Number: applied/pending

3. Classification(s):

§878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

(a) Identification. (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide. (2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

(b) Classification. Class II.

Device Class: Class II for all requested indications
Classification Panel: General and Plastic Surgery & Others
Product Code(s): GEX

4. Section 514 Compliance

Zap Lasers, LLC intends to comply fully with the general controls authorized under Sections 501, 502, 510, 516, 518, and 520 of the Food, Drug, and Cosmetic Act.

5. Performance Standards

United States Food and Drug Administration mandated performance standards for this device exist and are provided under Sections 21 CFR 1010 & 1020, with permissible deviations relative to Laser Notice 50, dated July 26, 2001. The device also complies with IEC60601-1:1995+A1+A2, IEC60601-2-22:1995, and IEC60825-1:1993+A1+A2. In addition, various voluntary performance standards are utilized. Voluntary standards utilized include Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and cGMP & ISO 9000 series quality regulations.

6. *Special Controls:*

All Class II devices are subject to Special Controls.

.. *Labeling:*

The laser system discussed in this premarket notification will be manufactured by Zap Lasers, LLC and labeled as such. Zap Lasers, LLC will market the system exclusively to healthcare facilities, physicians and dentists. In addition to the usual package and identification labeling, the following additional Warnings, Cautions & Precautions statements are displayed as appropriate on or within the device packaging. They are repeated here for ease of use.

Warning: Federal (United States) Law restricts this device to sale by or on the order of a physician or dentist only.

9. *Predicate Device (legally marketed comparison device)*

Zap Lasers, Inc. believes that the following surgical laser systems are substantially equivalent to the *Styla MicroLase™/OrthoLase™*- surgical diode system.

1. SOFT LASE G2 (K021227, ZAP Lasers, Inc.); 2. ODYSSEY NAVIGATOR (K062258, Ivoclar Vivadent, Inc.) and 3. *EZLase* (K061898, BioLase Technology, Inc.)

10. *Summary of Equivalence:*

There are no unique applications, indications, material or specifications presented herein. Evidence of equivalence has been demonstrated through:

- The *Styla MicroLase™/StylaOrtho™* intended use and indications for use were previously cleared by FDA for the predicate devices.
- The technical characteristics of the *Styla MicroLase™/StylaOrtho™* are similar to those of the cleared Odyssey Navigator and the EZLase.
- Laser output values of the *Styla MicroLase™/StylaOrtho™* are well within previously cleared values of the predicate dental laser system as described.
- The predicate devices and other previously cleared laser systems with similar power outputs have a proven safety and effectiveness in the treatment of the claimed indications.
- Safety and performance testing.

Therefore, the *Styla MicroLase™/StylaOrtho™* is substantially equivalent to its predicate devices cited above and raises no new safety and/or effectiveness issues.

11. *Device Description:*

The progress achieved in recent years in fiber optics and diode lasers technology has made it possible to have commercial devices with multi-watt output power in near-infrared spectrum from about 0.5-mm diameter single-core fiber.

This laser technology is now being used in many areas of medicine and dentistry, particularly oral surgery, arthroscopy, gastroenterology, general surgery, dermatology and plastic surgery. The intended uses of these laser devices include hemostasis, incision, excision,

ablation, vaporization, and coagulation of tissue. In dentistry, usage of laser devices ranges from cosmetic surgery to treating periodontal disease.

As the dental laser industry grows, there is an increased demand for portable soft tissue lasers. In today's market, customers want a more portable laser solution to avoid office clutter and to reduce setup time. It has also become apparent that a relatively low-power laser (2.0 maximum watts and 808 nm) covers the vast majority of laser surgical requirements. The Styla MicroLaser™/ StylaOrtho™ are the first soft-tissue laser developed as a handheld unit. It is wireless, lightweight, easy to set up, simple to use, requires less power, and cost efficient.

With the Styla MicroLaser™/StyloOrtho™ Zap Lasers introduces a miniature X-Y adjusting module for coupling a diode laser with a disposable fiber. Fiber accuracy is better than 5 um and the alignment is extremely stable. A module with a specific lens was developed by Zap Lasers in order to achieve such precision and alignment. Such a design greatly simplifies the fiber management and setup of operatory time as the fiber is attached into the tip allowing this item to be disposable and simple to be used. No fiber scoring is needed as the disposable tip is provided already scored to decrease setup tip and user's error.

Laser and Control Box:

The Laser and Control Box comprise the following major modules:

The laser diode assembly contains one single emitter laser diode of 2.0 watt output power (Class IV laser) lasing at 808 nm. The diode laser is directly coupled to a lens and aligned to the fiber optic inside the removable tips, using (patent pending) a 2 axis laser alignment system. It also contains a 5 mW power, 650 nm laser diode coupled to the same fiber optic. The laser's visible light is designed to aid the user to aim the tip of the delivery fiber onto the tissue.

The Styla MicroLaser™/StyloOrtho™ is designed to dissipate heat during normal operation and may feel warm to the touch after prolonged use. The laser module is mounted towards the tip of the unit, which acts as a heat sink during normal operation. The temperature is monitored by a sensor that prevents overheating.

Laser power controller provides electric power to the diodes in continuous wave and pulsed mode. It supplies about 2 VDC and current up to 4A to the diodes. The controller contains a high efficiency DC to DC converter that converts the battery voltage to the precise voltage needed for laser operation. This ensures that the majority of the energy is used for light and not converted into heat.

The delivery tips with fiber built in consist of 400 micron core multi-mode optical fiber, and a precise alignment mechanism. The fiber is factory installed into the tip and requires no installation by the end user.

The foot-switch is a standard (UL-approved) commercial foot-switch that provides hands-free ON/OFF capabilities. This switch controls initiation/termination of laser power from the distal end of the delivery fiber wirelessly.

12. Applicant Name & Address:

Zap Lasers, LLC
2621 Pleasant Hill Road
Pleasant Hill, CA 94523

13. Company Contact:

Jay Goble, DDS
Zap Lasers, LLC
2621 Pleasant Hill Road
Pleasant Hill, CA 94523
Phone: 888-876-4546
Fax: 925-930-6776

14. Submission Correspondent

Jay Goble, DDS
Zap Lasers, LLC
2621 Pleasant Hill Road
Pleasant Hill, CA 94523

15. Manufacturing Facility:

The devices are physically manufactured at ZAP Laser, LLC premises in Pleasant Hill, CA. The devices are manufactured by ZAP Lasers, LLC for distribution in the U.S.A.

16. Sterilization, Packaging & Storage Information:

The diode laser device is not supplied sterile. The disposable plastic hand piece tips are supplied non-sterile by the manufacturer and are to be discarded in an infectious waste container (SHARPS) after each use. There is no re-use or re-sterilization procedure indicated.

Packaging materials are typical medical grade tubes, plastic trays, peel-type pouches of the generic mylar/non-woven sandwich variety etc. All packages should be intact upon receipt. Packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. If the package or product is damaged, the product should not be used and should be returned. Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

Zap Lasers, LLC
% Underwriters Laboratories Inc.
Mr. Morten Christensen
455 East Trimble Road
San Jose, California 95131

Re: K081214
Trade/Device Name: Styla MicroLaser[™]/StylaOrtho[™]
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and
in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 20, 2008
Received: March 24, 2008

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

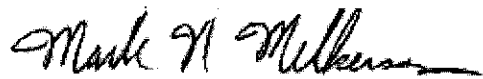
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tab 2
Indications for Use Statement

Device Name: Styla MicroLaser™/StylaOrtho™

K081214

Indication for Use:

The Styla MicroLaser™/StylaOrtho™ is to provide the ability to perform intraoral soft tissue dental, general, oral maxilla-facial and cosmetic surgery. The Styla MicroLaser™/StylaOrtho™ is intended for ablating, incising, excising, vaporizing and coagulation of soft tissues using a contact fiber optic delivery system.

The device will be used in the following areas: general and cosmetic dentistry otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery. The following are the oropharyngeal indications for use for which the device will be marketed:

- Excision and Incision Biopsies
- Hemostatic assistance
- Treatment of Aphthous Ulcers
- Frenectomy
- Frenotomy
- Gingival Incision and Excision
- Gingivectomy
- Gingivoplasty
- Incising and Draining of Abscesses
- Operculectomy
- Oral Papillectomy
- Removal of Fibromas
- Soft Tissue Crown Lengthening
- Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- Tissue retraction for Impression
- Vestibuloplasty
- Light activation of bleaching materials for teeth whitening
- Laser-assisted bleaching/whitening of teeth

Prescription Use ✓
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Evaluation and Safety (OIVD)

Neil R. P. Dyle
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K081214